

## **REMARKS**

### **1. The Amendments and the Support Therefor**

Two claims (claims 2 and 9) have been canceled, no new claims have been added, and claims 1, 8, and 10 have been amended to leave claims 1, 3-6, 8, 10-16, 18-21, 58, 60-75, and 78-83 in the application. No new matter has been added by the amendments or new claims, wherein:

- ***Independent claim 1*** has been amended to incorporate features recited in claim 2;
- ***Claim 8*** is amended to incorporate its dependent claim 9 (now canceled), and to correct the §112(2) issue noted in the Office Action (with support for the claimed matter being found, for example, in FIG. 2);
- ***Claim 10*** is amended to conform dependency in view of the cancellation of its parent claim 9.

### **2. Pages 2-3 of the Office Action: Rejection of Claim 8 under 35 USC §112(2)**

As noted above, claim 8 is amended to correct the §112(2) issue (as well as incorporating dependent claim 9, now canceled).

### **3. Pages 3-5 of the Office Action: Rejection of Claims 1, 5, 6, 8-11, 17-21, and 68-71 under 35 USC §103 in view of U.S. Patent 7,025,742 to Rubinstein et al.**

Initially, it is noted that while the §103 rejections at pages 3-5 of the Office Action begin by stating that claims 1, 2, 5, 6, 8-15, 18-21, 58, 60, 62, and 64-71 are rejected under 35 USC §103 in view of U.S. Patent 7,025,742 to *Rubinstein et al.* alone, a subset of these claims – specifically claims 2, 12-15, 58, 60, 62, and 64-67 – are then not discussed in pages 3-5, and are subsequently rejected at pages 5-6 in view of *Rubinstein et al.* in combination with U.S. Patent 5,643,195 to Drevet et al. Thus, it is assumed that claims 2, 12-15, 58, 60, 62, and 64-67 are not in fact rejected under 35 USC §103 in view of U.S. Patent 7,025,742 to *Rubinstein et al.* alone.

The remaining rejections of claims 1, 5, 6, 8-11, 17-21, and 68-71 under 35 USC §103 in view of U.S. Patent 7,025,742 to *Rubinstein et al.* are overcome for the following reasons.

**Independent Claim 1** has been amended to recite that at least a portion of the piston face is defined by a deformable diaphragm, a feature which is not present in *Rubinstein et al.* (wherein the piston 196 and valve member 194 of FIG. 16 simply displace on a spring 200 within a bore in the housing 182). As will be discussed at greater length in Section 4 of this Response (below), when the claimed invention is placed out of mind and *Rubinstein et al.* and the other art of record is fairly considered, it cannot fairly be said that an ordinary artisan would contemplate modifying *Rubinstein et al.* to attain the invention of claim 1 as amended, and thus claim 1 (and its dependent claims 5, 6, 11, and 17-21) are unobvious.

**Regarding Claims 8 and 10,** the matter of these claims is not seen to be described by, or obvious in view of, *Rubinstein et al.* (alone or in combination with the other art of record). To illustrate, claim 8 recites the use of a deformable-membrane mask on the piston, wherein a cutout in the mask aligns with the drain port to allow passage of fluid when the valve is open. None of the references of record show or suggest a mask / deformable membrane of this nature, and it cannot fairly be said that an ordinary artisan would contemplate or foresee such an arrangement after review of the references of record. Claim 8 (and its dependent claim 10) is therefore unobvious.

**Regarding Claims 68-71,** these depend from independent claim 58, which recites the use of a deformable diaphragm (one having a first face adjacent the upstream side). Claim 58 is rejected at pages 5-6 of the Office Action in view of *Rubinstein et al.* in combination with U.S. Patent 5,643,195 to *Drevet et al.* It is therefore assumed that these claims were intended to be rejected in view of *Rubinstein et al.* and *Drevet et al.*, and these will be discussed in Section 4 below.

**4. Pages 5-6 of the Office Action: Rejection of Claims 2, 12-15, 58, 60, 62, and 64-71 under 35 USC §103(a) in view of U.S. Patent 7,025,742 to Rubinstein et al. and U.S. Patent 5,643,195 to Drevet et al.**

Kindly withdraw these rejections, since the claimed invention cannot be deemed obvious when the proper analysis is applied. Looking to the obviousness analysis mandated by MPEP 2142:

To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical “person of ordinary skill in the art” when the invention was unknown and just before it was made. In view of all factual information, the

examiner must then make a determination whether the claimed invention “as a whole” would have been obvious at that time to that person. Knowledge of applicant’s disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the “differences,” conduct the search and evaluate the “subject matter as a whole” of the invention. The tendency to resort to “hindsight” based upon applicant’s disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

As further explained by the Federal Circuit and the Board of Appeals, any conclusion of obviousness must be supported by a statement convincingly explaining why an ordinary artisan would truly be led by the art to conceive the invention. See, e.g., *Ex parte Whalen*, 89 USPQ2d 1078, 1084 (Bd. Pat. App. & Int. 2008):<sup>1</sup>

The U.S. Supreme Court recently held that rigid and mandatory application of the “teaching-suggestion-motivation,” or TSM, test is incompatible with its precedents. *KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 [82 USPQ2d 1385] (2007). The Court did not, however, discard the TSM test completely; it noted that its precedents show that an invention “composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.*

The Court held that the TSM test must be applied flexibly, and take into account a number of factors “in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed.” *Id.* at 1740-41. Despite this flexibility, however, the Court stated that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements in the way the claimed new invention does.” *Id.* “To facilitate review, this analysis should be made explicit.” *Id.* . . .

The KSR Court noted that obviousness cannot be proven merely by showing that the elements of a claimed device were known in the prior art; it must be shown that those of ordinary skill in the art would have had some “apparent reason to combine the known elements in the fashion claimed.” *Id.* at 1741.

See also MPEP 2143.01, part IV (noting that the mere fact that “the references relied upon teach that

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<sup>1</sup> See also MPEP 2142:

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that “rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”

all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references.”)

Here, the Office Action alleges:

[I]t would have been obvious to one of ordinary skill in the art at the time of invention to modify the flow control system of Rubinstein with Drevet's diaphragm-based piston biasing system in order to provide a well-known, alternate means for controlling fluid flow through the valve in response to upstream fluid pressure.

Kindly step back, place the invention of *independent claims 1 and 58* out of mind, and consider whether this is truly the case if *Rubinstein*, *Drevet*, and the other references are fairly and objectively considered. Why would one truly consider modifying *Rubinstein* to have a diaphragm bias the piston rather than a spring? Stated differently, what is the “apparent reason to combine” demanded by *KSR*? As noted at column 14 lines 55-58, *Rubinstein* seeks to provide a linear relationship between fluid pressure and displacement, and *Rubinstein*'s coil spring provides such a relationship. In contrast, a diaphragm – which has different areas stretching / deforming by different amounts, and whose deformability depends in part on the density / compressibility of adjacent media – does not necessarily have a linear response. Moreover, *how* would one modify *Rubinstein* to incorporate a diaphragm? Use of a diaphragm is practically incompatible with *Rubinstein*'s structure: it simply isn't seen how one could incorporate a diaphragm into *Rubinstein* (in particular, a diaphragm exposed to upstream fluid) and still have *Rubinstein*'s piston 196 and valve member 194 mate with the bore in the housing 182, and operate in the desired manner. Thus, kindly consider: would an ordinary artisan who had no knowledge of the claimed invention, but who knew of *Rubinstein* and *Drevet*, truly contemplate the claimed invention? If so, why? More importantly, how would *Rubinstein* and *Drevet* be combined – what is the form of the device that the artisan would conceive?

Regarding claims 66-67, please refer to the discussion of claims 8-9 in the foregoing Section 3 of this Response: the art of record does not show a deformable mask having a cutout therein, nor would such matter be obvious to an ordinary artisan.

**5. Pages 6-7 (Section 5) of the Office Action: Rejection of Claims 3, 4, 16, 61, and 63 under 35 USC §103(a) in view of U.S. Patent 7,025,742 to Rubinstein et al., U.S. Patent 5,643,195 to Drevet et al., and U.S. Patent 5,192,265 to Drake et al.**

These claims are submitted to be allowable for at least the same reasons as claims 1 and 58, from which these claims ultimately depend.

**6. Pages 8-10 (Section 6 and “Response to Arguments”) of the Office Action: Rejection of Claims 72-75 under 35 USC §103(a) in view of U.S. Patent 7,025,742 to Rubinstein et al., U.S. Patent 5,643,195 to Drevet et al., and U.S. Patent 6,379,340 to Zinger**

Kindly reconsider these rejections. There is no dispute with some of the points raised by the Office Action, e.g., that rotational cutout valves are indeed well-known. However, this does not alter the requirements for a proper *prima facie* case of obviousness, as discussed in Section 3 above: the Office Action must explain why an ordinary artisan who has no knowledge of the claimed invention, but who knew of the cited art, would foresee or contemplate the claimed invention. Further, this explanation must be an objective and plausible one, rather than a conclusory dismissal. Here, if the claimed invention is placed out of mind and the cited references are reviewed, it cannot fairly be said that an ordinary artisan would contemplate or consider the claimed invention. Considering that *Rubenstein et al.* and *Drevet et al.* operate (automatically) on the basis of linear motion, and *Zinger et al.* is in essence little more than a (manual) rotating stopcock, it is simply not seen how one *would* truly and objectively consider incorporating features of *Zinger et al.* into the *Rubenstein / Drevet* combination, much less why one *could* do so. Kindly consider: again placing the claimed invention out of mind to avoid hindsight, how does one adapt *Rubenstein* and/or *Drevet* to accommodate the allegedly “equivalent” rotating arrangement of *Zinger*? Or, considered differently, how could one having no knowledge of the invention truly devise a shunt having the characteristics of claims 72-75, *while also* having the recited features of parent claim 1 (in particular, the piston and diaphragm arrangement)? We note that during the interview of January 14, 2010, it was the undersigned attorney’s understanding that the Office found these points to be persuasive: that it wasn’t seen how one would (or could) come up with a rotationally-displacing piston coupled to a diaphragm, wherein

the diaphragm displaces the piston (and faces the upstream side), and having the remaining recited features. The Office has apparently reconsidered this position, but the Office Action does not detail why – and more importantly how – one would come up with the claimed arrangement starting from the prior art. Again, there is no dispute that rotational valves are well known, but a rotational valve using a diaphragm in the recited manner is *not* known, and it is not understood how the Office reasons that an ordinary artisan would (or could) devise the claimed invention starting with the cited references.

*Secondly*, regarding the rejections’ use of MPEP 2144.06 as their supporting rationale, and the statement (at page 9 of the Office Action) that “[t]he examiner takes the position that it is well known in the art that rotationally and axially displaceable cutout valves are equivalents in the art”, it must be kept in mind that MPEP 2144.06 cautions:

In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant’s disclosure or the mere fact that the components at issue are functional or mechanical equivalents.

Here, the alleged equivalency is *not* recognized in the art, nor is *Zinger et al.* (nor U.S. Patent 5,540,668 to *Wilson et al.*, noted briefly in the rejection) truly a functional or mechanical equivalent to *Rubenstein et al.* or *Drevet et al.*:

- *Rubenstein et al.* automatically “switches” flow between input and output ports on or off depending on the upstream pressure (and valve motion is linear).
- *Drevet et al.* automatically “switches” flow between input and output ports on or off depending on differences between upstream and downstream pressure (and valve motion is linear).
- *Zinger et al.* (and *Wilson et al.*) are basically rotational stopcocks which manually switch flow from an input to *different outputs* depending on the operator’s preference, with valve motion being rotational.

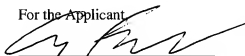
This is not a matter of the simple substitution of one structure for an art-recognized equivalent: how could one truly modify *Rubenstein et al.* or *Drevet et al.* to operate rotationally (and automatically)

in dependence on upstream pressure?<sup>2</sup> Again, while the cited references all deal with valves, it should be apparent that not all valves are “equivalents,” and here there are significant structural and functional differences such that one component / concept cannot readily be “swapped” for the other.<sup>3</sup> Thus, the rationale for the rejection is erroneous.

**7. In Closing**

If any questions regarding the application arise, please contact the undersigned attorney. Telephone calls related to this application are welcomed and encouraged. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

For the Applicant



**Craig A. Fieschko, Reg. No. 39,668**  
CUSTOMER NO. 39061  
DEWITT ROSS & STEVENS S.C.  
2 E. Mifflin St., Suite 600  
Madison, WI 53703-2865  
Telephone: (608) 395-6722  
Facsimile: (608) 252-9243  
cf@dewittross.com

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<sup>2</sup> While the Office Action states at page 9 that “it would have been within the scope of one of ordinary skill in the art at the time of invention to modify Rubenstein’s device to displace rotationally”, is this really so? With respect, we can’t comprehend the form of such a modification, much less how it would come about. Thus, if the Office maintains its conclusions, could the Office kindly support its conclusions with a sketch or explanation of the structure / operation of such a “rotational Rubenstein”?

<sup>3</sup> Furthermore, stepping back to the first point above, these differences are such that it simply cannot fairly be said that an ordinary artisan who did not know of the claimed invention would devise the claimed invention after review of *Zinger et al.*, *Drevet*, and *Rubinstein*: there is no apparent route whereby one could successfully combine the features of these inventions to attain the claimed invention.